AMENDED IN SENATE MARCH 27, 2006

SENATE BILL No. 1301

Introduced by Senator Alquist

February 16, 2006

An act to amend ~~Section 1266~~ *Sections 1266 and 1280.1* of, to add Sections 1279.1, 1279.2, and 1279.3 to, and to repeal and add Section 1279 of, the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

SB 1301, as amended, Alquist. Health facilities: reporting and inspection requirements.

Existing law provides for the inspection, licensure, and regulation of health care facilities by the State Department of Health Services, including, among other facilities, general acute care hospitals, acute psychiatric hospitals, special hospitals, and long-term health care facilities, some of which are collectively referred to as nursing homes. Existing law requires that all licensed general acute care hospitals maintain a medical records system, as specified, that organizes all medical records for each patient under a unique identifier, and develop and implement policies and procedures to ensure that relevant portions of patients' medical records can be made available within a reasonable period of time to respond to the request of a treating physician, other authorized medical professionals, authorized representatives of the department, or any other person authorized by law to make such a request, taking into consideration the physical location of the records and hours of operation of the facility where those records are located, as well as the interests of the patients.

Existing law establishes licensing and annual renewal fees for health facilities, and requires the department, by March 1 of each year, to

make certain information regarding the methodology and calculations used to determine these fee amounts available to interested parties, upon request.

This bill instead would require the department to make this information available by February 17, and would further require the department to make the information available to the budget and relevant policy committees of the Legislature without the need for a request. The bill would revise requirements relating to the department's preparation of a staffing and systems analysis to ensure efficient and effective utilization of the fees collected and proper allocation of departmental resources.

Existing law requires the department to conduct periodic inspections of health facilities for which a license or special permit has been issued, to insure the quality of care. Existing law exempts certain health facilities that are certified to participate in the federal Medicare and Medicaid Programs from these inspections. Existing law also authorizes the department to contract for outside personnel to perform inspections of health facilities as the need arises.

This bill would revise the above inspection provisions, including requiring that a health facility licensed as a general acute care hospital, acute psychiatric hospital, or special hospital, at least once every 3 years, or as often as necessary to ensure the quality of care being provided. The bill would require the department to ensure that inspections conducted pursuant to the bill are not announced in advance of the inspection date. The bill would authorize the department to conduct a joint inspection with an outside entity under contract with the department, but would require the department to conduct a separate unannounced inspection if the outside entity provides notice in advance of the periodic inspection.

This bill would require the department to inspect for compliance with state law and regulation during state and federal periodic inspections, notwithstanding any other provision of law. This bill would require the department to take various actions related to the reporting to, and the investigation by, the department of any medical error that results in a serious injury to, or the ~~suspicious~~ death of, a patient that occurs at a ~~licensed~~ *general* acute care hospital or acute psychiatric hospital. The bill would require a general acute care hospital, acute psychiatric hospital, or special hospital to report to the department any medical error, as defined, ~~that results in the serious injury or suspicious deathof a patient,~~ within 48 hours of its

occurrence. *The bill would authorize the department to assess specified civil penalties against a licensee for failure to report a medical error as required by the bill.*

This bill would require the department to conduct an onsite inspection or investigation within 48 hours or 2 business days of a complaint involving the threat of imminent danger of death or serious bodily harm at a general acute care hospital, an acute psychiatric hospital, or a special hospital. The bill would require the outcome of investigations or inspections conducted in accordance with these provisions to be posted on the department's Internet Web site and available in written form, *by January 1, 2009*.

The bill would require the costs of administering and implementing certain of its provisions to be paid from funds derived from licensing fees paid by general acute care, acute psychiatric, and special hospitals.

Violation of provisions relating to the operation of health facilities is a crime. Therefore, by imposing new and revised requirements on health facilities, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 1266 of the Health and Safety Code is amended to read:

1266. (a) Each new and renewal application for a license for the health facilities listed below shall be accompanied by an annual fee as set forth below.

(1) The annual fee for a general acute care hospital, acute psychiatric hospital, special hospital, and chemical dependency recovery hospital, based on the number of licensed beds, is as follows:

1–49 beds	$460 plus $8 per bed
50–99 beds	$850 plus $8 per bed
100 or more beds	$1,175 plus $8 per bed

(2) The annual fee for a skilled nursing facility, intermediate care facility, and intermediate care facility/developmentally disabled, based on the number of licensed beds, is as follows:

1–59 beds	$2,068 plus $26 per bed
60–99 beds	$2,543 plus $26 per bed
100 or more beds	$3,183 plus $26 per bed

(3) The fees provided in this subdivision shall be adjusted, commencing July 1, 1983, as proposed in the state department's 1983–84 fiscal year Health Facility License Fee Report to the Legislature. Commencing July 1, 1984, fees provided in this subdivision shall be adjusted annually, as directed by the Legislature in the annual Budget Act.

(b) (1) By February 17 of each year, the State Department of Health Services shall make available to the budget and relevant policy committees of the Legislature, and upon request, to other interested parties, information regarding the methodology and calculations used to determine the fee amounts specified in this section, the staffing and systems analysis required under subdivision (e), program costs associated with the licensing provisions of this division, and the actual numerical fee charges to be implemented on July 1 of that year. This information shall specifically identify federal funds received, but not previously budgeted for, the licensing provisions of this division that are used to offset the amount of General Fund money to be recovered through license fees. The information shall also identify the purpose of federal funds received for any additional activities under the licensing provisions of this division that are not used to offset the amount of General Fund money.

(2) The methodology and calculations used to determine the fee amounts shall result in fee levels in an amount sufficient to provide revenues equal to the sum of the following:

(A) The General Fund expenditures for the fiscal year beginning on July 1 of that year, as specified in the Governor's proposed budget, less license fees estimated to be collected in

that fiscal year by the licensing provisions of this division, excluding licensing fees collected pursuant to this section.

(B) The amount of federal funds budgeted for the fiscal year ending June 30 of that year for the licensing provisions of the division, less federal funds received or credited, or anticipated to be received or credited, during that fiscal year for that purpose.

The methodology for calculating the fee levels shall include an adjustment that takes into consideration the actual amount of license fee revenue collected pursuant to this section for that prior fiscal year.

(3) If the Budget Act provides for expenditures that differ by 5 percent from the Governor's proposed budget, the Department of Finance shall adjust the fees to reflect that difference and shall instruct the State Department of Health Services to publish those fees in accordance with subdivision (d).

(c) The annual fees determined pursuant to this section shall be waived for any health facility conducted, maintained, or operated by this state or any state department, authority, bureau, commission, or officer, or by the Regents of the University of California, or by a local hospital district, city, county, or city and county.

(d) The department shall, within 30 calendar days of the enactment of the Budget Act, publish a list of actual numerical fee charges as adjusted pursuant to this section. This adjustment of fees, any adjustment by the Department of Finance, and the publication of the fee list shall not be subject to the rulemaking requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. If the published list of fees is higher than that made available to interested parties pursuant to subdivision (b), the affected health facilities may choose to pay the fee in the amount presented at the public hearing and to defer payment of the additional increment until 60 days after publication of the list of fees pursuant to this subdivision.

(e) Prior to the establishment of the annual fee, the department shall prepare a staffing and systems analysis to ensure efficient and effective utilization of fees collected, proper allocation of departmental resources to licensing and certification activities, survey schedules, complaint investigations, enforcement and appeal activities, data collection and dissemination, surveyor

training, and policy development. The analysis shall demonstrate that the department has sufficient surveyors, other appropriate professionals, and administrative support personnel to fulfill the requirements of state and federal law for timely inspections, complaint investigations within the timeframes specified by law and regulation, and timely investigations of reports of medical errors. The analysis shall include information on the proportion of inspections and investigations that were completed in a timely manner during the preceding year, as well as the waiting times for change of ownership and new licensees.

The analysis under this subdivision shall be included in the information made available pursuant to subdivision (b), and shall include all of the following:

(1) The number of surveyors and administrative support personnel devoted to the licensing and certification of health care facilities.

(2) The percentage of time devoted to licensing and certification activities for the various types of health facilities.

(3) The number of facilities receiving full surveys and the frequency and number of followup visits.

(4) The number and timeliness of complaint investigations.

(5) Data on deficiencies and citations issued, and numbers of citation review conferences and arbitration hearings.

(6) Training courses provided for surveyors.

(7) Other applicable activities of the licensing and certification division.

The analysis shall also include recommendations for administrative changes to streamline and prioritize the survey process, complaint investigations, management information systems, word processing capabilities and effectiveness, consumer information system, and surveyor training.

The annual staffing and systems analysis shall be presented to the Health Care Advisory Committee and the Legislature prior to the establishment and adoption of the annual fee.

(f) The annual fee for a congregate living health facility shall initially, and until adjusted by the Legislature in a Budget Act, be based on the number of licensed beds as follows:

1–3 beds	$ 800
4–6 beds	$1,000

7–10 beds	$1,200
11–15 beds	$1,500
16 or more beds	$1,700

Commencing July 1, 1991, fees provided in this subdivision shall be adjusted annually, as directed by the Legislature in the annual budget.

(g) The annual fee for a pediatric day health and respite care facility, as defined in Section 1760.2, shall initially, and until adjusted by the Legislature in a Budget Act, be based on the number of licensed beds as follows:

1–3 beds or clients	$ 800
4–6 beds or clients	$1,000
7–10 beds or clients	$1,200
11–15 beds or clients	$1,500
16 or more beds or clients	$1,700 plus $50 for each additional bed or client over 16 beds or clients

Commencing July 1, 1993, fees provided in this subdivision shall be adjusted annually, as directed by the Legislature in the annual Budget Act.

(h) The department shall, in consultation with affected provider representatives, develop a specific proposal by July 1, 1995, to do all of the following:

(1) Revise the health facility licensure fee methodologies in a manner that addresses the fee methodology and subsidy issues described in the State Auditor Report Number 93020, Issues 2 and 3.

(2) Ensure the validity and reliability of the data systems used to calculate the license fee.

(3) Address the subsidy of licensing and certification activities regarding health facilities for which the annual license fee is waived.

(4) Develop a licensing and certification special fund into which all fees collected by the state department, for health facility licensing, certification, regulation, and inspection duties, functions, and responsibilities, shall be deposited.

SEC. 2. Section 1279 of the Health and Safety Code is repealed.

SEC. 3. Section 1279 is added to the Health and Safety Code, to read:

1279. (a) Every health facility for which a license or special permit has been issued, except a health facility, as defined in subdivisions (b) to (k), inclusive, of Section 1250, that is certified to participate either in the Medicare Program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act, or in the Medicaid Program under Title XIX (42 U.S.C. Sec. 1396 et seq.) of the federal Social Security Act, or both, shall be periodically inspected by a representative or representatives appointed by the state department, depending upon the type and complexity of the health facility or special service to be inspected.

(b) If the health facility is deemed to meet standards for certification to participate in either the Medicare Program or the Medicaid Program, or both, because the health facility meets the standards of an agency other than the Health Care Financing Administration, then, in order for the health facility to qualify for the exemption from periodic inspections provided in this section, the inspection to determine that the health facility meets the standards of an agency other than the Health Care Financing Administration shall include participation by the California Medical Association to the same extent as it participated in inspections as provided in Section 1282 prior to September 15, 1992.

(c) Except as provided in subdivision (d), inspections shall be conducted no less than once every two years and as often as necessary to ensure the quality of care being provided.

(d) ~~(1)~~ For a health facility specified in subdivision (a), (b), or (f) of Section 1250, inspections shall be conducted no less than once every three years, and as often as necessary to ensure the quality of care being provided.

~~(2) For a health facility specified in subdivision (a), (b), or (f) of Section 1250, that reports a serious medical error consistent with Section 1279.1, an inspection shall be conducted annually until that facility has had no reported serious medical errors for a period of 18 months.~~

(e) During the inspection, the representative or representatives shall offer any advice and assistance to the health facility as they deem appropriate.

(f) For acute care hospitals of 100 beds or more, the inspection team shall include at least a physician, registered nurse, and persons experienced in hospital administration and sanitary inspections. During the inspection, the team shall offer such advice and assistance to the hospital as it deems appropriate.

(g) The department shall ensure that a periodic inspection conducted pursuant to this section is not announced in advance of the date of the inspection. An inspection may be conducted jointly with inspections by entities specified in Section 1282. However, if the department conducts an inspection jointly with an entity specified in Section 1282 that provides notice in advance of the periodic inspection, the department shall conduct an additional periodic inspection that is not announced or noticed to the health facility.

(h) Notwithstanding any other provision of law, the department shall inspect for compliance with provisions of state law and regulation during a state or federal periodic inspection, including, but not limited to, an inspection required under this section.

SEC. 4. Section 1279.1 is added to the Health and Safety Code, to read:

1279.1. (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report any medical error ~~that results in serious injury or suspicious death of a patient to the~~ *to the* department not later than 48 hours after the ~~serious injury or death~~ *medical error* has occurred.

~~(b) A medical error shall be defined as defined by the Institute of Medicine's 1999 report, "To Err is Human: Building a Safer Health System."~~

(b) A medical error includes, but is not limited to, any of the following:

(1) Surgical events, including the following:

(A) Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. Reportable events under this subparagraph do not include situations requiring prompt action that occur in the course of surgery or situations whose urgency precludes obtaining informed consent.

(B) Surgery performed on the wrong patient.

(C) A surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or an urgent situation that precludes the obtaining of informed consent.

(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

(E) Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

(2) Product or device events, including the following:

(A) Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.

(B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

(C) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(3) Patient protection events, including the following:

(A) An infant discharged to the wrong person.

(B) Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision making capacity.

(C) A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility.

(4) Care management events, including the following:

(A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

(B) A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(C) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

(D) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.

(E) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.

(F) A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

(G) A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

(5) Environmental events, including the following:

(A) A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.

(B) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.

(C) A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

(D) A patient death associated with a fall while being cared for in a health facility.

(E) A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

(6) Criminal events, including the following:

(A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

(B) The abduction of a patient of any age.

(C) The sexual assault on a patient within or on the grounds of a health facility.

(D) The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

(c) The facility shall inform the patient or the party responsible for the patient of the report at the time the report is made.

SEC. 5. Section 1279.2 is added to the Health and Safety Code, to read:

1279.2. (a) (1) In any case in which the department receives a report from a facility pursuant to Section 1279.1, or a written or oral complaint involving a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250, that creates a threat of imminent danger of death or serious bodily harm, the department shall make an onsite inspection or investigation within 48 hours or two business days, whichever is greater, of the receipt of the report or complaint and shall complete that investigation within 45 days.

(2) The department shall ensure that the licensing and certification branch conducts an unannounced inspection of any health facility that has reported a medical error pursuant to Section 1279.1, not less than once a year.

(b) In any case in which a medical error results in the serious injury or ~~suspicious~~ death of a patient and the department is able

to determine from the information available to it that there is no threat of imminent danger of death or serious bodily harm to that patient or other patients, the department shall complete an investigation of the report within 45 days.

(c) The department shall notify the complainant and licensee in writing of the department's determination as a result of an inspection or report.

(d) For purposes of this section, "complaint" means any oral or written notice to the department, other than a report from the health facility, of an alleged violation of applicable requirements of state or federal law or an allegation of facts that might constitute a violation of applicable requirements of state or federal law.

(e) The costs of administering and implementing this section shall be paid from funds derived from existing licensing fees paid by general acute care hospitals and acute psychiatric hospitals.

SEC. 6. Section 1279.3 is added to the Health and Safety Code, to read:

1279.3. ~~The~~ *By January 1, 2009, the* department shall provide information regarding the outcomes of inspections and investigations conducted pursuant to Section 1279.1, both on the department's Internet Web site and in written form in a manner that is readily accessible to consumers in all parts of California, and that protects patient confidentiality. *The information shall include compliance history information, as well as information regarding each of the events described in Section 1279.1.*

SEC. 7. Section 1280.1 of the Health and Safety Code is amended to read:

1280.1. (a) *(1)* If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 fails to correct a deficiency within the time specified in a plan of correction, the state department may assess the licensee a civil penalty in an amount not to exceed fifty dollars ($50) per patient affected by the deficiency for each day that the deficiency continues beyond the date specified for correction. The civil penalties shall be assessed only for deficiencies that pose an immediate and substantial hazard to the health or safety of patients. If the licensee disputes a determination by the state department regarding alleged failure to correct a deficiency or regarding the reasonableness of the proposed deadline for correction, the

licensee may, within 10 days, request a hearing pursuant to Section 100171. Penalties shall be paid when appeals pursuant to those provisions have been exhausted.

~~(b) This section~~

(2) Paragraph (1) shall not apply to a deficiency for which a facility was cited prior to January 1, 1994.

(b) If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 fails to report a medical error pursuant to Section 1279.1, the department may assess the licensee a civil penalty in an amount not to exceed one hundred dollars ($100) for each day that the medical error is not reported following the initial 48-hour period provided for in subdivision (a) of Section 1279.1. If the licensee disputes a determination by the department regarding alleged failure to report a medical error, the licensee may, within 10 days, request a hearing pursuant to Section 100171. Penalties shall be paid when appeals pursuant to those provisions have been exhausted.

~~SEC. 7.~~

SEC. 8. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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